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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/020,816      | 12/12/2001  | Nicholas D. Donato   | 270/138             | 8918             |

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| EXAMINER |
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TATE, CHRISTOPHER ROBIN

|          |              |
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| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/020,816

Applicant(s)

Donato

Examiner

Christopher Tate

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

Art Unit: 1654

### **DETAILED ACTION**

Claims 1-58 are presented for examination on the merits.

#### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite for the following reasons:

- Within the plant kingdom the term "Euphorbiae" (line 1) denotes a family of plants containing numerous genera therein and, thus, it is unclear what this term is actually defining as it does not properly define the particular genus known as --*Euphorbia*--. In addition, as evidenced by the Internet website -- <http://www.plantzafrica.com/plantefg/euphorobesa.htm> --, this family term is misspelled (the correct spelling is --*Euphorbiaceae*--). It would appear that Applicants meant to recite the genus of this plant species and, therefore, it is suggested that throughout the claims (as well as throughout the instant specification and the title - see specification objection below) this family term be omitted and replaced with the plant genus --*Euphorbia*--.

Art Unit: 1654

- The process recited in claim 1 is very unclear because it is missing one or more essential steps therefrom (see, e.g., MPEP 2172.01) and, thus, is also incomplete. For example, it is unclear by the first step if the sample prepared in this step is the latex material itself or the remainder of the plant after removing the latex material therefrom (in addition, the phrase "the latex material" in the first step lacks antecedent basis). In the second step, the essential solvent(s) by which the sample is dissolved should be particularly defined as this is clearly essential with respect to extracting the active anti-cancer agents from the plant sample. In the fourth step, it is completely unclear as to what the phrase "purifying said pulp fraction" actually is defining - e.g., is this attempting to define purifying a compound from the pulp fraction, removing debris from the pulp fraction, or something else (i.e., in what manner is the pulp fraction actually purified)? Further, it is unclear as to what actually constitutes "said extract" - e.g., is it some purified compound, or product obtained from the fourth step, is it what has been removed from the purified pulp fraction, or something else? Since the process steps in preparing the "crude extract" as described in Example 1 of the instant specification (pages 10-11) are clearly essential in providing an extract having the anti-cancer functional effects instantly claimed, they must be adequately defined in the claim language itself. It is, therefore, strongly suggested that claim 1 be expanded upon so as to recite the essential steps necessary in preparing the instantly disclosed crude extract (using Example 1 as a guide) so as to clearly define a complete overall process for preparing the instantly disclosed/demonstrated plant extract to overcome this rejection.

Art Unit: 1654

Claims 41-58 recite the limitation "the process" in line 1 of each. There is insufficient antecedent basis for this limitation in these claims as they all depend directly or indirectly from claim 32 which recites "A method". Thus, it is unclear if the "process" recited in claims 41-58 are directed solely to the process of claim 1 (from which claim 32 depends) or to the method of claim 32.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

### *Specification*

The disclosure is objected to because of the following:

For the reasons set forth above (under U.S.C. 112, second paragraph), the term "Euphorbiae" should be omitted and replaced with --*Euphorbia*-- throughout the specification as well as the title, wherever this term appears.

Appropriate correction is required.

The claims are free of the art. The closest prior art of record is that of Aylward (US 6,432,452 - which corresponds to WO 9908994) which is drawn to anti-cancer agents obtained from sap extracts of three different *Euphorbia* spp., but does not reasonably teach or suggest obtaining or using an anti-cancer extract from *Euphorbia obesa* as instantly disclosed/claimed.

Art Unit: 1654

### **Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.



Christopher R. Tate  
Primary Examiner, Group 1654